FDA and Industry OMUFA Implementation Meeting
April 24, 2024

Agenda:

- **FDA Updates**
- **Industry Updates and Discussion Topics**

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Michael Bailey	CHPA
Michael Bernstein	CDER (ORP)	Barbara Kochanowski	CHPA
Anuj Shah	CDER (ORP)	David Spangler	CHPA
Theresa Michele	CDER (OND)	Gil Roth	PBOA
Karen Murry	CDER (OND)	Cornell Stamoran	Catalent
Suzanne Strayhorn	CDER (OND)		
Celia Peacock	CDER (OND)		
Andrea Frydl	CDER (OCOMM)		
Angela Granum	CDER (OM)		
Matthew Brancazio	CDER (OM)		
Grace Carmouze-Cunningham	CDER (OEP)		
Kimberly Taylor	CDER (OSP)		

FDA Updates:

FDA indicated the following:

- Now that the Deemed Final orders are complete, progress is being made on a number of forecast topics.
- First face-to-face monograph meeting was held at White Oak Campus.
- An update on the number of monograph meetings was provided for fiscal years 2021, 2022, 2023 and 2024. FDA is exceeding meeting timeline goals in FY23 and 24.
- The number of monograph meetings have increased significantly in the first two quarters of 2024.
- The monograph meeting reviews have been very labor intensive due to novel issues raised requiring additional legal and policy input.

FDA reviewed the status for publication of final guidance documents.

FDA provided an update on the fiscal year 2024 Federal Register notice (FRN) as it relates to facility user fee rates. FDA also discussed the direction provided within the FRN with regard to hand sanitizer manufacturers (Section III.B).

FDA provided updates on hiring.

FDA provided an update on communications.

Industry Updates and Discussion Topics:

FDA and Industry discussed the following:

- March 19, 2024, FDA launched a Q & A podcast on phenylephrine.
- FDA provided feedback regarding pre-OMOR meetings.
- Industry requested additional information regarding the 2023 Pediatric Cough/Cold Letter to Congress by the FDA. FDA agreed to share the letter with industry.